DEPARTMENT OF HEALTH & HUMAN SERVICES

National Institutes of Health
National Institute of Mental Health
6001 Executive Blvd., Rm. 8154
Bethesda, Maryland 20892

Date: April 2, 2003

Subject: Request for Small Business Innovative Research (SBIR) Phase I Proposal under National Institute of Mental Health (NIMH) Request for Proposals (RFP) No. NIMH-03-SBIR-Phase I

Dear Sirs:

The purpose of this solicitation is to invite Phase I contract proposals from small business concerns that have the expertise to contribute to the mission of the NIMH. Included are instructions for proposal preparation and a description of the proposal review process.

The mission of the NIMH is to diminish the burden of mental illness through research. To achieve this goal, the NIMH funds basic research, clinical studies, and services delivery research concerning any aspect of behavioral and mental disorders (including HIV prevention and neuro AIDS research). Ultimately, this research will lead to greater understanding, better treatment and rehabilitation or prevention of mental disorders. The NIMH is also concerned with the speedy dissemination and use of this knowledge through scientific communications and public education, and in its more effective implementation in practice and service delivery systems. The NIMH invites you to submit a Phase I SBIR Proposal under the following topics:

Topic 301: Development of Curriculum, Training Modules and Approaches to Increase Diversity of SBIR Technology Transfer Programs at the NIMH

Topic 302: Development of Educational Models and Procedures to Improve the Quality of Mental Health Services and Interventions Research Mentoring

Topic 303: Mental Health Science Education Materials for Social Work Faculty at Doctoral, Master's and Baccalaureate Programs

Topic 304: Use of Computer-based Technology to Deliver Effective HIV Prevention Interventions

The NIMH will accept Fast Track proposals on the following Topics: 301, 302, and 303. Please see Section IV below for submission instructions under the Fast Track option.

All proposals must be received by May 28, 2003 at 2:00 PM, Eastern Time, and must be marked: SBIR Phase I Proposal. Please submit one (1) original and ten (10) copies of your proposal and deliver the proposal to the following address:

If hand-delivered or delivery service
Contracts Management Branch
National Institute of Mental Health
Attn: Robin Hope-Williams
Contract Specialist
6001 Executive Boulevard
Rm. 8154, MSC 9661
Rockville, MD 20852-9661

If using U.S. Postal Service
Contracts Management Branch
National Institute of Mental Health
Attn: Robin Hope-Williams
Contract Specialist
6001 Executive Boulevard
Rm. 8154, MSC 9661
Bethesda, MD 20892-9661

This RFP does not commit the Government to pay any cost for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer (CO) is the only individual who can legally commit the Government to expenditure of public funds in connection with this proposed acquisition.

ANY DISCUSSION OF THIS RFP WITH ANY INDIVIDUAL(S) OUTSIDE THE CONTRACTS MANAGEMENT BRANCH, NIMH, MAY RESULT IN DISQUALIFICATION OF THE OFFEROR AND REJECTION OF ANY PROPOSAL SUBMITTED.

Any small business concern that intends to submit an SBIR proposal under this solicitation should provide the CO with early, written notice of its intent by completing the Proposal Intent Sheet in Attachment No. 1 of this solicitation. If a topic is modified or canceled before this Solicitation closes, only those companies that have expressed such intent will be notified. Questions about this requirement should be submitted (preferably via e-mail) to Robin Hope-Williams at rhwilli@mail.nih.gov, and marked "Offeror's Questions, Under RFP No. NIMH-03-SBIR-PhaseI". These questions should be submitted no later than May 1, 2003. Ms. Hope-Williams can also be contacted at 301-443-2696 or via fax 301-443-0501.

Sincerely,

/s/
Patricia L. Gibbons, Contracting Officer
Chief, Contracts Management Branch, ORM
National Institute of Mental Health, NIH

RFP Sections

ATTACHMENT 1 --- PROPOSAL INTENT SHEET - see last page of this RFP

APPENDIX A — PROPOSAL COVER SHEET – use for Phase I Proposals
APPENDIX B — ABSTRACT OF RESEARCH PLAN – use for Phase I and Fast Track Proposals
APPENDIX C — PRICING PROPOSAL – use for Phase I and Fast Track Proposals
APPENDIX D --- PHASE II TECHNICAL PROSPOSAL COVER SHEET – use for Fast Track Proposals
APPENDIX E --- STATEMENT OF WORK SAMPLE FORMAT – use for Fast Track Proposals
APPENDIX F --- SUMMARY OF RELATED ACTIVITES – use for Phase I and Fast Track Proposals
APPENDIX G --- PROPOSAL SUMMARY AND DATA RECORD – use for Fast Track Proposals

The Appendices noted above are in Adobe Acrobat Reader fillable format.

SMALL BUSINESS INNOVATION RESEARCH (SBIR) CONTRACT PROPOSALS

I. GENERAL PROGRAM DESCRIPTION

The SBIR program recently was reauthorized by the enactment of the Small Business Reauthorization Act of 2000, (Public Law 106-554. The Public Health Service (PHS), Department of Health and Human Services (HHS), and certain other Federal agencies must reserve 2.5 percent of their current fiscal year extramural budgets for research or research and development (R/R&D) for a SBIR program. The objectives of the SBIR program include stimulating technological innovation in the private sector, strengthening the role of small business in meeting Federal R/R&D needs, increasing private sector commercialization of innovations developed through Federal SBIR R&D, increasing small business participation in Federal R&D, and fostering and encouraging participation by socially and economically disadvantaged small business concerns and women-owned small business concerns in the SBIR program.

The SBIR program consists of three separate phases:

The objective of Phase I is to determine the scientific or technical feasibility and commercial merit of the proposed research or R&D efforts and the quality of performance of the small business concern, prior to providing further Federal support in Phase II. Phase I awards normally may not exceed $100,000 for direct costs, indirect costs, and profit (fixed fee) for a period normally not to exceed 6 months.

The objective of Phase II is to continue the research or R&D efforts initiated in Phase I. Funding shall be based on the results of Phase I and the scientific and technical merit and commercial potential of the Phase II proposal. Phase II awards normally may not exceed $750,000 for direct costs, indirect costs, and negotiated fees for a period normally not to exceed two years. That is, generally, a two-year Phase II project may not cost more than $750,000 for that project.

The objective of Phase III, where appropriate, is for the small business concern to pursue with non-Federal funds the commercialization objectives resulting from the results of the research or R&D funded in Phases I and II. In some Federal agencies, Phase III may involve follow-on, non-SBIR funded R&D or production contracts for products or processes intended for use by the U.S. Government.

SBIR PROGRAM ELIGIBILITY

Organizational Criteria: Each organization submitting a proposal under the SBIR program must qualify as a small business concern (defined in Section II.) Access to special facilities or equipment in another organization is permitted (as in cases where the SBIR awardee has entered into a sub-contractual agreement with another institution for a specific, limited portion of the research project). However, *research space occupied by an SBIR contractor organization must be space that is available to and under the control of the SBIR contractor for the conduct of its portion of the project*. Where there is indication of sharing of common employees, a determination will be made on a case-by-case basis of whether or not such sharing constitutes control or the power to control.

Whenever a proposed SBIR project is to be conducted in facilities other than those of the offeror organization, a letter must be submitted *with* the proposal stating that leasing/rental arrangements have been negotiated for appropriate research space (i.e., space that will be available to and under the control of the SBIR contractor organization).

This letter must be signed by an *authorized official of the organization whose facilities are to be used for the SBIR project.* It also must include a description of the facilities and, if appropriate, equipment that will be leased/rented to the offeror organization. All SBIR contract proposals will be reviewed with the above considerations in mind. *If it appears that an offeror organization does not meet eligibility requirements, the NIMH will request a size determination of the organization from the cognizant Small Business Administration (SBA) regional office. The evaluation of the proposal for scientific merit will be deferred until the SBA provides a determination*.

Principal Investigator Criteria. The primary employment of the principal investigator must be with the offeror at the time of contract award and during the conduct of the proposed project. The principal investigator is the single individual designated in the contract proposal with responsibility for the scientific and technical direction of the project. Primary employment means that *more than one half of the principal investigator's time* is spent in the employ of the small business concern. *Primary employment with a small business concern precludes fulltime employment at another organization*.

In the event that the principal investigator: (1) is a less-than-full-time employee of the small business, (2) is concurrently employed by another organization, or (3) gives the appearance of being concurrently employed by another organization, whether for a paid or unpaid position, at the time of submission of the proposal, *it is essential that documentation be submitted with the proposal to verify his/her eligibility*. If the principal investigator also is employed or appears to be employed by an organization other than the offeror organization (e.g., a university, a nonprofit

research institute, or another company), a letter must be provided by the *non-offeror organization* confirming that the principal investigator will, if awarded an SBIR contract, become a less-than-half-time employee of such organization and will remain so for the duration of the SBIR project. If the principal investigator is employed by a university, the Dean's Office must provide such a letter. If the principal investigator is employed by another for-profit organization, the corporate official must sign the letter. This documentation is required for every proposal that is submitted, even one that is a revision of a previously submitted proposal.

Performance Site Criteria. For both Phase I and Phase II, the research or R&D project activity *must be performed in its entirety in the United States (see Section II. Definitions)*.

Market Research. *The NIMH will not support any market research under its SBIR program*. Neither will it support studies of the literature that will lead to a new or expanded statement of work. Literature searches where the commercial product is a database are acceptable. For purposes of the SBIR program, "market research" is the systematic gathering, recording, computing, and analyzing of data about problems relating to the sale and distribution of the subject of the research project. It includes various types of research, such as the size of potential market and potential sales volume, the identification of consumers most apt to purchase the products, and the advertising media most likely to stimulate their purchases. However, "market research" does not include activities under a research plan or protocol that require a survey of the public as part of the objective of the project to determine the impact of the subject of the research on the behavior of individuals.

II. DEFINITIONS [Back to Page 2]

Clinical Research. NIH defines human clinical research as: **(1)** Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies. **(2)** Epidemiologic and behavioral studies. **(3)** Outcomes research and health services research. Note: Studies falling under Exemption for human subjects research are not considered clinical research by this definition.

Commercialization. The process of developing markets and producing and delivering products for sale (whether by the originating party or by others); as used here, commercialization includes both government and private sector markets.

Contract. An award instrument establishing a binding legal procurement relationship between a funding agency and the recipient, obligating the latter to furnish an end product or service and binding the agency to provide payment therefore.

Essentially Equivalent Work. This term is meant to identify "scientific overlap," which occurs when: (1) substantially the same research is proposed for funding in more than one proposal (contract proposal or grant application) submitted to the same Federal agency; OR (2)

substantially the same research is submitted to two or more different Federal agencies for review and funding consideration; OR (3) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more proposals or awards, regardless of the funding source.

Innovation. Something new or improved, including research for: (1) development for new technologies, (2) refinement of existing technologies, or (3) development of new applications for existing technologies. For purposes of this solicitation, an example of "innovation" would be new medical or biological products, for improved value, efficiency, or costs.

Key Personnel Engaged on Project. This term is meant to identify those individuals who contribute in a substantive way to the scientific development or execution of the project, whether or not salaries are requested.

Prototype. A model of something to be further developed that includes designs, protocols, questionnaires, software, devices, etc.

Research or Research and Development (R/R&D). Any activity that is:

1. A systematic, intensive study directed toward greater knowledge or understanding of the subject studied.

2. A systematic study directed specifically toward applying new knowledge to meet a recognized need.

3. A systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Small Business Concern. A small business concern is one that, at the time of award of Phase I, meets all of the following criteria:

1. Is independently owned and operated, is not dominant in the field of operation in which it is proposing, has its principal place of business located in the United States, and is organized for profit;

2. Is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by United States citizens or lawfully admitted permanent resident aliens;

3. Has, including its affiliates, a *number of employees not exceeding 500*, and meets the other regulatory requirements found in 13 CFR Part 121. Business concerns, other than investment companies licensed, or state development companies qualifying under the Small Business Investment Act of 1958, 15 U.S.C. 661, *et seq.,* are affiliates of one another when either directly or indirectly:

a. One concern controls or has the power to control the other; or
b. A third party or parties controls or has the power to control both. Control can be exercised through common ownership, common management, and contractual relationships. The term "affiliates" is defined in greater detail in 13 CFR 121.3-2(a). The term "number of employees" is defined in 13 CFR 121.3-2(t). *Business concerns include, but are not limited to, any individual (sole proprietorship), partnership, corporation, joint venture, association, or cooperative*.

Joint Ventures or Limited Partnerships. Joint ventures and limited partnerships are eligible provided the entity created qualifies as a small business concern as defined in this Solicitation.

Socially and Economically Disadvantaged Individual. A member of any of the following groups:

- Black Americans
- Hispanic Americans
- Native Americans
- Asian-Pacific Americans
- Subcontinent Asian Americans
- Other groups designated from time to time by SBA to be socially disadvantaged
- Any other individual found to be socially and economically disadvantaged by SBA pursuant to Section 8(a) of the Small Business Act,15 U.S.C. 637(a)

Socially and Economically Disadvantaged Small Business Concern. A socially and economically disadvantaged small business concern:

1. Is one that is at least 51 percent owned by: (a) an Indian tribe or a native Hawaiian organization, or (b) one or more socially and economically disadvantaged individuals; and

2. Whose management and daily business operations are controlled by one or more socially and economically disadvantaged individuals.

Subcontract. Any agreement, other than one involving an employer-employee relationship, entered into by a Federal Government prime contractor calling for supplies or services required solely for the performance of the prime contract or another subcontract.

United States. The 50 states, the territories and possessions of the U.S., the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.

Woman-Owned Small Business Concern. A small business concern that is at least 51 percent owned by a woman or women who also control and operate it. "Control" in this context means exercising the power to make policy decisions. "Operate" in this context means being actively involved in the day-to-day management.

III. PHASE I PROPOSAL PREPARATION INSTRUCTIONS AND REQUIREMENTS

A. LIMITATIONS ON LENGTH OF PROPOSAL

SBIR Phase I proposals shall not exceed a total of *25 single-spaced pages*, including Appendix A, B, and C. Pages should be of standard size (8 l/2" X 11"), and the font should be no smaller than 10-point. Excluded from the 25-page limitation are cover letters, letters of commitment from collaborators and consultants (and any letters to determine eligibility). Unless specifically solicited by a CO, no other appendices may be submitted, and if submitted, they will not be considered in the evaluation of scientific and technical merit.

B. PROPOSAL COVER SHEET

Complete the form identified as Appendix A and use it as the first page of the proposal. *No other cover sheet should be used*.

- ***Topic Number.*** Provide the appropriate numerical designator of the research topic
- ***Project Title.*** Select a title that reflects the substance of the project. Do not use the title of the topic that appears in the Solicitation.

C. ABSTRACT OF RESEARCH PLAN

Complete the form identified as Appendix B, and insert it as the second page of each proposal. Abstracts of successful proposals will be published by NIMH and, therefore, should not contain proprietary information. The abstract should include a brief description of the problem or opportunity, specific aims, and a description of the effort. Summarize anticipated results and potential commercial applications of the proposed research.

D. RESEARCH PLAN

Any research proposal involving the collection of information, such as surveys or interviews, of more than nine respondents will require clearance by the U.S. Office of Management and Budget. Therefore, it is not practical to propose such an activity for Phase I, which normally has only a six-month duration.

Beginning on page three of the proposal, discuss in the order indicated the following elements:

1. ***Identification and Significance of the Problem or Opportunity***. Provide a clear statement of the specific technical problem or opportunity addressed.

2. ***Technical Objectives***. State the specific objectives of the Phase I effort, including the technical questions it will try to answer to determine the feasibility of the proposed approach.

3. ***Work Plan***. Provide a detailed plan for the R&D to be carried out, including the experimental design, procedures, and protocols to be used. Address the objectives and the questions stated in *Item 2* above. Discuss in detail the methods to be used to achieve each objective or task.

4. ***Related Research or R&D***. Describe significant research or R&D that is directly related to the proposal, including any conducted by the principal investigator/project manager or by the proposing firm. Describe how it relates to the proposed effort and any planned coordination with outside sources.

5. ***Relationship with Future R&D***.

    a. State the results expected from the proposed approach.
    b. Discuss the significance of the Phase I effort in providing a foundation for the Phase II R/R&D effort.

6. ***Potential Commercial Applications***. Describe why the proposed project appears to have potential commercial applications, and whether and by what means the proposed project appears to have potential use by the Federal Government.

7. ***Key Personnel and Curriculum Vitae (CV)***. Identify key personnel, including their directly related education, experience, and bibliographic information. Where vitae are extensive, focus on summaries of the most relevant experience or publications. Provide dates and places of employment and some information about the nature of each position or professional experience. Curriculum vitae must identify the current or most recent position.

8. ***Salary Rate Limitation***. Beginning with the HHS Appropriations Act of Fiscal Year (FY) 1990, direct salary rate limitations have been placed on the NIH contracts that support the NIH Extramural R&D activities. Direct salary is exclusive of overhead, fringe benefits, and general and administrative expenses. The FY 2003 HHS Appropriations Act, P.L. 108-7 was enacted on February 20, 2003. This Act provides funding for the HHS for FY-03. In so providing, Division G, Title H, General Provisions, Section 204 of P.L.108-7 states in pertinent part:

    "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse and Mental Health Services Administration shall be used to pay the salary of an individual, through a grant or other extramural mechanism, at a rate in excess of Executive Level I ($171,900)."

    The salary rate ceiling applies to cost-reimbursement contracts that meet the definition above and to their subcontracts. It also applies to fixed-price level-of-effort, time and material, and labor hour contracts, where the Government's purpose is to buy the direct effort of an individual **and** the contract is for a project supporting the NIH Extramural R&D activities. It does not apply to fixed-price completion contracts. The rate limitation does not restrict the salary that an organization might pay an individual working under an NIH contract; it merely limits the portion of that salary that may be paid with Federal funds. Additionally, the rate limitation does not apply to fees paid to consultants.

9. ***Consultants***. Involvement of consultants is strongly encouraged. Such use must be described in detail and supported by appropriate letters from each individual confirming his/her role in the project.

10. ***Facilities and Equipment***. Indicate where the proposed research will be conducted.

    a. *One of the performance sites must be the offeror organization*. Describe the facilities to be used; identify the location; and briefly indicate their capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Include clinical, computer, and office facilities of the offeror and those of any other performance sites to be used in the project. List the most important equipment items already available for this project, noting location and pertinent capabilities of each. Any equipment and products purchased with Government funds shall be American made, to the extent possible.

    b. *Title to Equipment.* Title to equipment purchased with Government funding by the SBIR awardee in relation to project performance vests upon acquisition in the Federal Government. However, the Government may transfer such title to an SBIR awardee upon expiration of the project where the transfer would be more cost-effective than recovery of the property.

E. CURRENT AWARDS AND PENDING PROPOSALS/APPLICATIONS

A small business concern may not submit both a contract proposal and a grant application for essentially the same project. The only exception would be the submission of a grant application after a contract proposal has been evaluated and is no longer being considered for award.

While it is permissible, with proposal notification, to submit identical proposals or proposals containing a significant amount of essentially equivalent work (as defined in this solicitation) for consideration under numerous Federal program solicitations, it is unlawful to enter into contracts or grants requiring essentially equivalent effort.

If a firm elects to submit identical proposals or proposals containing a significant amount of essentially equivalent work under other Federal program solicitations, include a statement in each such proposal indicating the information requested in items 1-10 set forth below. In addition, provide the information requested in items 1-10 on (a) active funding through contracts, grants, and cooperative agreements from public or private sponsors; (b) contract proposals and grant and cooperative agreement applications pending review or funding; and (c) contract proposals and grant and cooperative agreement applications about to be submitted.

1. Name and address of the funding source.
2. Type of award (contract, grant, cooperative agreement) and identifying number.
3. Title of research project.
4. Name and title of principal investigator or project manager.
5. Hours per week on the project by the principal investigator or project manager.
6. Annual costs proposed or awarded.

7. Entire period of support.
8. Date of proposal/application submission or date of award.
9. Title, number, and date of solicitations under which proposals or applications were submitted or awards received.
10. The specific applicable research topic for each SBIR proposal or application submitted or award received. *Specifically identify those projects that are SBIR*.

F. PROPOSED COST BREAKDOWN

Complete the form identified as Appendix C. A blank sheet of paper can be substituted for page 2 of the appendix if it addresses all items on page 2. Page 3 of Appendix C, General Information, should not be included with the proposal. The cost breakdown should appear as the last section of the proposal. *If some items on this form do not apply to the proposed project, they need not be completed*.

- Under NIMH RFP No. NIMH-03-SBIR-PhaseI.
- If supplies are proposed, provide the quantities and the price per unit.
- Under "Direct Labor," *list all key personnel by name*. Support personnel may be consolidated into categories or labor classes, e.g., research assistants or data processing clerks.
- If travel is proposed, provide the following details on "Exhibit A – Supporting Schedule": destination(s); duration of trip(s); number of travelers; and cost per trip, broken down by cost elements, e.g., airfare, lodging, and meals.
- If consultants are proposed, provide name(s), rate(s), and number of hours/days.
- If a subcontract is proposed, provide the same type of detailed cost breakdown as required for Appendix C. *Also provide a letter of commitment from the subcontractor.*
- Use "Exhibit A – Supporting Schedule" (page 2 of Appendix C, or a blank sheet of paper) to itemize and justify all major cost elements.

G. JUST IN TIME PROCEDURES

The NIMH has initiated special *"just in time" procedures* that are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. ***Just in time procedures will be implemented during negotiations with offerors***. The following are among the documentation that may be part of the "just in time" procedures:

- ***Data Universal Numbering System (DUNS) number.*** A DUNS number may be obtained immediately, at no charge, by calling Dun and Bradstreet on (800) 333-0505.
- ***Travel Policy.*** The offeror's written travel policy
- ***Annual Financial Report.*** The offeror's most recent annual financial report and or an annual audit report.
- ***Total Compensation Plan.*** Salary and fringe benefits of professional employees under service contracts.
- ***Data Substantiating the Costs and Prices Proposed.*** That is, payroll documentation, vendor quotes, invoice prices, etc.

- **Submission of Electronic Funds Transfer Information (EFT) -** submission of this information satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer—Other than Central Contractor Registration.
- ***Representation and Certifications*** **–**Negotiated Contract, only one completed and signed copy.
- ***Indirect Rates*** – explain the components of proposed rates. Indicate if rates have been negotiated with a federal agency or if they are based on an audit. A copy of the rate agreement with a federal agency or the audit report may be requested under "just in time".
- ***Payroll sheets*** – or other evidence to support proposed labor rates. Include information regarding organizational policies for the review of salaries and the granting of increases. For proposed consultants include evidence that consultants receive the hourly/daily rate from other federal agencies, or from other organizations for similar work.
- ***Certify*** – that the offeror has not previously been, nor is currently being, paid for essentially equivalent work by any agency of the Federal Government.

H. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH requires education on the protection of human research participants for all individuals identified as "key personnel" before funds are awarded for contract proposals involving human subjects. For information relating to this requirement, see the following notice (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html), which was published June 5, 2000 in the *NIH Guide for Grants and Contracts*. Prior to award, the selected contractor will be required to provide a description of education completed in the protection of human subjects for all key personnel. While NIH does not endorse programs, there are curricula available that can provide guidance or that can be modified to provide training in this area. See (http://ohsr.od.nih.gov/) for computer-based training developed for NIH that can be downloaded at no charge and modified for use. For information on facilitating education and developing curricula, see http://www.nih.gov/sigs/bioethics.

I. INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

It is NIH policy that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects (see http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-001.html) unless a clear and compelling rationale shows that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy applies to research subjects of all ages. The inclusion of women and members of minority groups and their subpopulations must be addressed in developing a research design appropriate to the scientific objectives of the study. Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects. Include a

description of the proposed outreach programs for recruiting women and minorities as participants.

All research projects involving human subjects are subject to the policy, whether or not they are exempt from human subject protections and Institutional Review Board (IRB) review requirements. All investigators proposing research involving human subjects should read the "NIH Guidelines On the Inclusion of Women and Minorities as Subjects in Clinical Research", which was published in the *NIH Guide for Grants and Contracts (October 9, 2001)*

J. INCLUSION OF CHILDREN IN RESEARCH INVOLVING HUMAN SUBJECTS

It is NIH policy that children must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. *For purposes of this policy, a "child" is defined as an individual under the age of 21 years*. Contracts involving human subjects include categories that would otherwise be exempt from the HHS regulations for the Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts. Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations, whether or not such research is otherwise exempt from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion.

In the technical proposal, the offeror should create a section titled "Participation of Children." Provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in research Involving Human Subjects," which was published in the *NIH Guide for Grants and Contracts* on March 6, 1998, and is available at http://grants1.nih.gov/grants/guide/notice-files/not98-024.html

K. REQUIREMENT FOR ADEQUATE ASSURANCE OF PROTECTION OF HUMAN SUBJECTS

The HHS regulations for the Protection of Human Subjects, 45 CFR 46 (as amended), provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS. The requirement is that an approved assurance of compliance with the regulations must be on file with the Office for Human Research Protections (OHRP), DHHS (formerly Office for Protection from Research Risks (OPRR), NIH) before an HHS award can be made.

Neither an Institutional Review Board (IRB) review nor an OHRP -approved Assurance is required at the time the proposal is submitted or at the time that the proposals are peer reviewed.

The review group will consider carefully whether the proposal includes necessary safeguards to protect the rights and welfare of research participants. *No contract award can be made without IRB approval.* Therefore, following NIH peer review and notification of an Institute's decision to proceed with negotiations and funding, the offeror should proceed with IRB review. On request of the awarding component, OHRP will contact the offeror to provide detailed instructions for filing the necessary documents to request a Single Project Assurance (SPA). The regulations define a "human subject" as a "living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable state and local law and is not directly regulated by 45 CFR 46 (as amended). **In doubtful cases, prior consultation with the Office for Human Research Protections (OHRP), DHHS, (301) 496-7041, may be of assistance.**

Inappropriate designations of the noninvolvement of human subjects in an SBIR project may result in delays in the review of a proposal. The OHRP, on behalf of HHS, will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. Any SBIR contract involving human subjects that is awarded as a result of a proposal submitted in response to this solicitation will include the following clauses:

1. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 (as amended) and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), DHHS. The Contractor further agrees to provide certification at least annually that the institutional review board has reviewed and approved the procedures which involve human subjects in accordance with 45 CFR Part 46 (as amended) and the Assurance of Compliance.

2. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

3. If at any time during performance of this contract, the CO determines, in consultation with the OHRP, DHHS, that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (1) and (2) above, the CO may immediately suspend, in whole or in part, work and further payments under this contract

until the Contractor corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the CO's written notice of suspension, the CO may, in consultation with OHRP, DHHS, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Health and Human Services Human Subject Assurances.

L. NEEDLE EXCHANGE

The HHS Fiscal Year 2003 Appropriations Act continues a restriction on using contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. (See Section 505 (P.L. 108-7, Division G, Title V-General Provisions)

M. BAN ON HUMAN EMBRYO RESEARCH The HHS Fiscal Year 2003 Appropriations Act continues the ban on funding of human embryo research. Currently, contract funds may not be used for: (1) the creation of a human embryo or embryos for research purposes, or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells. Additionally, Federal funds may not be used for cloning of human beings. (See Section 510 (P.L. 108-7, Division G, Title V-General Provisions)

N. RESEARCH USING HUMAN PLURIPOTENT STEM CELLS

In signing the application Face Page, the duly authorized representative of the applicant organization certifies that if research using human pluripotent stem cells is proposed, the applicant organization will be in compliance with the National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells published in the Federal Register http://www.nih.gov/news/stemcell/stemcellguidelines.htm

O. REQUIREMENT FOR ADEQUATE ASSURANCE OF COMPLIANCE WITH THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS

The PHS Policy on Humane Care and Use of Laboratory Animal (Policy) establishes a number of requirements in research activities involving live, vertebrate animals. It stipulates that an offeror organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS -supported research activities. The PHS Policy defines "animal" as "any live, vertebrate animal used or intended for use in research, research training, experimentation or biological testing or for related purposes." An offeror organization proposing to use animals in PHS- supported activities must file a written Animal Welfare Assurance with the Office of Laboratory Animal Welfare (OLAW), NIH. When an offeror proposes research that involves animals, but the offeror does not have an Animal Welfare Assurance on file with OLAW, on request of the awarding component, OLAW will contact the offeror and provide detailed instructions for filing the necessary document.

Neither an Institutional Animal Care and Use Committee (IACUC) nor an OLAW-approved Assurance is required at the time the proposal is submitted. Institutions having an Assurance with OLAW are encouraged to have an IACUC review before submitting the proposal and should furnish verification of IACUC approval with the proposal. However, an Assured organization may submit the verification of IACUC review after proposal submission but before the Initial Technical Review is initiated. If verification is not received before the Initial Technical Review meeting, the awarding component will not allow the review of the proposal.

No award for research involving animals will be made unless the offeror organization is operating in accord with an approved Animal Welfare Assurance and provides verification that the IACUC has reviewed and approved the proposed activity in accordance with PHS Policy. 48 CFR Part PHS 352 requires that any contract involving live, vertebrate animals, awarded as a result of a proposal submitted in response to this solicitation include the following clauses:

1. Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The Contractor shall furnish evidence of such registration to the CO.

2. The Contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

3. The Contractor agrees that the care and use of any live, vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care and Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 *et seq.* and 9 CFR Subchapter A, Parts 1-3). In case of conflict between standards, the more stringent standard shall be used.

4. If at any time during performance of this contract, the CO determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) above, the CO may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the CO's written notice of suspension, the CO may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Public Health Service Animal Welfare Assurances.

   The Contractor may request registration of its facility and a current listing of licensed dealers from the Animal Care Sector Office of the Animal and Plant Health

Inspection Service (APHIS), USDA, for the sector in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program, may be obtained by contacting: Animal Care Staff, USDA/APHIS, 4700 River Road, Unit 84, Riverdale, MD 20737, (301) 734-4980

Offerors proposing research that involves live, vertebrate animals will be contacted by OLAW and given detailed instructions on filing a written Animal Welfare Assurance. Offerors are encouraged to visit the OLAW website at http://grants1.nih.gov/grants/olaw/olaw.htm for additional information. OLAW may be contacted at the National Institutes of Health at (301) 594-2289.

IV. FAST-TRACK INITIATIVE [Back to Page 2]

The "Fast-Track" initiative is a parallel review option available to those small business concerns (offeror organizations) whose proposals satisfy additional criteria that enhance the probability of the project's commercial success (Refer to Section IX, "Research Topics," for notation.).

The Fast-Track initiative is an opportunity for small business concerns to submit both a Phase I and Phase II proposal for concurrent peer review. This initiative also has the potential to minimize any funding gap between Phase I and Phase II.

Fast-Track Proposal Process

To identify the proposals as Fast-Track, check the box marked "Yes" next to the words "Fast-Track Proposal" shown on the Phase I Proposal Cover Sheet (Appendix A).

The small business concern must submit both a Phase I and a Phase II proposal for concurrent initial peer review and evaluation. The Fast-Track proposal must consist of the following parts:

1. ***Phase I Proposal.*** Prepared in accordance with Section III. Phase I Proposal Preparation Instructions and Requirements, and addressing all factors stated in the evaluation criteria for Phase I proposals.
2. ***Phase II Proposal.*** Prepared in accordance with Section V, Fast-Track Phase II Proposal Preparation Instructions and Requirements and addressing all factors stated in the evaluation criteria (Section VI) for Phase II proposals.
3. ***Product Development Plan.*** A concise document (limited to ten pages), which addresses each of the following areas:

    a. Company information, including size, specialization area(s), products with significant sales, and history of previous Federal and non-Federal funding, regulatory experience, and record of commercializing SBIR or other research;

    b. Value of SBIR project, including lay description of key technology objectives, current competition, and advantages to competing products or services, and any funding commitments from private sector or non-SBIR funding sources;

c. Commercialization plans, milestones, target dates, market analyses of market size, and estimated market share after first year sales and after five years. The plan should state the amount and approximate dates that Phase III funds will be made available; and

d. Patent status or other protection of project intellectual property.

Letters of Commitment. Offerors are encouraged to seek letters of interest or commitment(s) of funds and/or resources from an investor or partner organization for commercialization of the product(s) or service(s) resulting from the SBIR contract.

Fast-Track proposals that do not contain all parts described above will be redirected for Phase I consideration only.

The Phase I and Phase II proposals will be scored individually, and the scores for both phases will be totaled. Following the initial peer review, Fast-Track proposals may receive secondary review by the program staff of the respective NIH awarding component. Fast-Track Phase II proposals may be funded following submission of the Phase I final report, and a determination that the Phase I objectives were met, feasibility was demonstrated, and funds are available.

V. FAST-TRACK PHASE II PROPOSAL PREPARATION INSTRUCTIONS AND REQUIREMENTS

1. **LIMITATIONS ON LENGTH OF PROPOSAL** SBIR Phase II proposals generally should not exceed a total of 150 single-spaced pages, including all enclosures and attachments. Pages should be of standard size (8 1/2" x 11") and the font should be no smaller than 10 point. Excluded from the page limitation are cover letters and letters from collaborators and consultants.

2. **TECHNICAL PROPOSAL FORMAT AND CONTENT REQUIREMENTS**

   1. Phase II Technical Proposal Cover Sheet- Use Appendix D.
   2. Table of Contents
   3. **Abstract of the Research Plan**- Use Appendix B. State the broad, long-term objectives and specific aims. Do not include any proprietary information. Briefly and concisely describe the research design and methods for achieving these goals.
   4. **Anticipated Results of Phase I Effort** - briefly discuss and summarize the objectives of your Phase I effort, the research activities to be carried out, and the anticipated results.
   5. **Research Plan**

      a. *Detailed Approach and Methodology*- provide an explicit detail description of the Phase II approach. This section should be the major portion of the proposal and must clearly show advancement in the project appropriate for Phase II. Indicate not only what is planned, but also how and where the work will be carried out. List all tasks in a logical sequence to precisely describe what is expected of the contractor in performance of the work. Tasks should contain detail to (1) establish parameters for the project; (2) keep the effort focused on meeting the objectives;

(3) describe end products and deliverables; and (4) describe periodic/final reports required to monitor work progress under the contract.

b. *Personnel*- list by name, title, department and organization, the extent of commitment to this Phase II effort, and detail each person's qualifications and role in the project. ***Provide curricula vitae for all key staff members,*** describing directly related education, experience, and relevant publications. Describe in detail any involvement of subcontractors or consultants, and ***provide curricula vitae for all key subcontractor staff. Also, include letters of commitment with proposed consultants confirming the extent of involvement and hourly/daily rate.***

c. *Resources*- list/describe all equipment, facilities and other resources available for this project, including the offeror's clinical, computer and office facilities/equipment at any other performance site that will be involved in this project. Briefly state their capacities, relative proximity and extent of availability to this effort. (***Any equipment specifically proposed as a cost to the contract must be justified in this section as well as detailed in the budget. Equipment and products purchased with Government funds shall be American-made, to the extent possible. Title to the equipment will vest in the Government.)***

VIII. *Other considerations* - provide a brief narrative of any unique arrangements, safety procedures in place, animal welfare issues, human subjects, etc. Note: If the research plan includes the use of human subjects or animals, refer to Section III, H of this solicitation for further guidance.

IX. *Appendices*

i. **Work Statement** - develop a Statement of Work. Create this from your detailed approach and methodology. It will be incorporated into the final contract document.

ii. **Product Development Plan** – Required for ALL Phase II and Fast-Track applications. Comply with requirements referred to in Section IV.3

6. **Summary of Related Activities** -use Appendix F.
7. **Technical Proposal Cost Information -** use Appendix C. Delete the fringe benefit costs, indirect costs and fee. Prepare a separate Appendix C for each year of the contract and a summary of the entire project.
8. **Number of Copies** -submit an original and 9 copies.

C. BUSINESS PROPOSAL FORMAT AND CONTENT REQUIREMENTS

1. **Cover Page** - use NIH Form 2043, Proposal Summary and Data Record, Appendix G.

2. **Breakdown of Proposal Estimated Costs, Fee and Labor Hours** - use Appendix C . Explain the basis for all costs and submit documentation to support all proposed costs

must be submitted. Prepare a separate Appendix C for each year of the contract and a summary of the entire project.

3. **Number of Copies** - submit an original and 4 copies.

VI. METHOD OF SELECTION AND EVALUATION CRITERIA [Back to Page 2]

A. EVALUATION PROCESS

Contract proposals are subjected to peer review by panels of scientists selected for their competence in relevant scientific and technical fields. The peer review panel will be responsible for evaluating proposals for scientific and technical merit. The peer review panel provides a rating, makes specific recommendations related to the scope, direction and/or conduct of the proposed research, and may provide a commentary about the funding level, labor mix and duration of the proposed contract project.

The NIMH program staff will also conduct a second level of review. The comments as well as those of the peer review panel will be presented during the negotiation/discussion phase of the award process. Recommendations of the peer review panel and program staff are based on judgments about not only the technical merit of the proposed research but also its relevance and potential contributions to the mission and programs of the awarding component. A Phase I or Phase II contract may be awarded only if the corresponding proposal has been recommended as technically acceptable by the peer review panel. ***Funding for any/all acceptable proposals is not guaranteed.***

B. TECHNICAL EVALUATION CRITERIA

In considering the technical merit of each proposal, the following factors will be assessed:

FACTORS FOR PHASE I PROPOSALS	WEIGHT
1. The soundness and technical merit of the proposed approach and identification of clear measurable goals (milestones) to be achieved during Phase I. (*Preliminary data are not required for Phase I proposals* .)	40%
2. The qualifications of the proposed principal investigator, supporting staff, and consultants.	20%
3. The potential of the proposed research for technological innovation.	15%
4. The potential of the proposed research for commercial application.	15%
5. The adequacy and suitability of the facilities and research environment.	10%

FACTORS FOR PHASE II PROPOSALS	WEIGHT
1. The scientific/technical merit of the proposed research, including adequacy of the approach and methodology, and identification of clear, measurable goals to be achieved during Phase II.	30%
2. The potential of the proposed research for commercialization and the adequacy of the Product Development Plan.	30%
3. The qualifications of the proposed principal investigator, supporting staff and consultants.	25%
4. The adequacy and suitability of the facilities and research environment.	15%

C. PROPOSAL DEBRIEFING

Offerors will be notified when they are no longer being considered for award. Offerors are entitled to a debriefing in accordance to FAR Subpart 15.5, which can be requested within three days of the receipt of the notification.

D. AWARD DECISIONS

Selection of an offeror for contract award will be based on an evaluation of proposals against four (4) factors. The factors in order of importance are: Ratings resulting from the scientific/technical evaluation process; Areas of high program relevance; Program balance (i.e., balance among areas of research); and Availability of funds.

Although technical factors are of paramount consideration in the award of a contract, cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

The NIMH is not under any obligation to fund any proposal or make any specific number of contract awards in a given research topic area. The NIMH may also elect to fund several or none of the proposals received within a given topic area. The SBIR contract process does not require establishing a competitive range or requesting final proposal revisions before reaching source selection decisions.

Proposals will be initially screened to determine their compliance with the administrative requirements of this Solicitation and their applicability to the research topic selected by the offeror. Using the technical evaluation factors described above in Section VI B., a peer review

panel will evaluate proposals passing the initial screening for technical merit and scientific acceptability, to determine the most promising approaches.

VII. CONSIDERATIONS [Back to Page 2]

A. AWARDS

1. The award instrument will be a contract.
2. A profit or fixed fee may be included in the proposal and the fee will be negotiated. A profit or fee is considered any amount in excess of actual direct and indirect cost incurred in the conduct of a project.
3. Phase I awards normally may not exceed $100,000 for direct costs, indirect costs, and profit (fixed fee) for a period normally not to exceed 6 months.

B. REPORTING & DELIVERABLES

Reporting and Deliverable Requirements – Phase I

Topic 301: Development of Curriculum, Training Modules and Approaches to Increase Diversity of SBIR Technology Transfer Programs at the NIMH

Finalized Work Plan- 5 copies- Within first 2 weeks of contract
Draft Final Report- 5 copies- Within first 5 months of contract
Final Report- 5 copies- Due at contract expiration
Monthly Progress- 2 copies, submitted within 2 weeks of month ending and with the monthly invoice(1 to PO, 1 to CO)
Presentations at NIMH- 2 visits, first visit shall be within the 1 month of contract award date to discuss the work plan and second visit shall be within the last month of contract to discuss the final report.

Topic 302: Development of Educational Models and Procedures to Improve the Quality of Mental Health Services and Interventions Research Mentoring

Finalized Work Plan- 5 copies- Within first 2 weeks of contract
Draft Final Report- 5 copies- Within first 5 months of contract
Final Report- 5 copies- Due at contract expiration
Monthly Progress- 2 copies, submitted within 2 weeks of month ending and with the monthly invoice(1 to PO, 1 to CO)
Presentations at NIMH- 2 visits, first visit shall be within the 1 month of contract award date to discuss the work plan and second visit shall be within the last month of contract to discuss the final report.

Topic 303: Mental Health Science Education Materials for Social Work Faculty at Doctoral, Master's and Baccalaureate Programs

Finalized Work Plan- 5 copies- Within first 2 weeks of contract
Draft Final Report- 5 copies- Within first 5 months of contract
Final Report- 5 copies- Due at contract expiration
Monthly Progress- 2 copies, submitted within 2 weeks of month ending and with the monthly invoice(1 to PO, 1 to CO)
Presentations at NIMH- 2 visits, first visit shall be within the 1 month of contract award date to discuss the work plan and second visit shall be within the last month of contract to discuss the final report.

Topic 304: Use of Computer-based Technology to Deliver Effective HIV Prevention Interventions

Finalized Work Plan- 5 copies- Within first 2 weeks of contract
Draft Final Report- 5 copies- Within first 5 months of contract
Final Report- 5 copies- Due at contract expiration
Monthly Progress- 2 copies, submitted within 2 weeks of month ending and with the monthly invoice(1 to PO, 1 to CO)
Presentations at NIMH- 2 visits, first visit shall be within the 1 month of contract award date to discuss the work plan and second visit shall be within the last month of contract to discuss the final report.

Reporting and Deliverable Requirements – Phase II

Topic 301: Development of Curriculum, Training Modules and Approaches to Increase Diversity of SBIR Technology Transfer Programs at the NIMH

Finalized Work Plan- 5 copies- Within first 2 weeks of Phase II contract
Draft Final Report- 5 copies- At least 3 weeks prior to the end of the contract
Final Report- 5 copies- Due at contract expiration
Monthly Progress- 2 copies, submitted within 2 weeks of month ending and with the monthly invoice(1 to PO, 1 to CO)
Presentations at NIMH- 3 visits: first visit shall be within 1 month of contract award date to discuss the work plan; second visit shall be during contract performance and; third visit within the last month of contract to discuss the final report.

Topic 302: Development of Educational Models and Procedures to Improve the Quality of Mental Health Services and Interventions Research Mentoring

Finalized Work Plan- 5 copies- Within first 2 weeks of Phase II contract
Draft Final Report- 5 copies- At least 3 weeks prior to the end of the contract
Final Report- 5 copies- Due at contract expiration
Monthly Progress- 2 copies, submitted within 2 weeks of month ending and with the monthly invoice(1 to PO, 1 to CO)

Presentations at NIMH- 3 visits: first visit shall be within 1 month of contract award date to discuss the work plan; second visit shall be during contract performance and; third visit within the last month of contract to discuss the final report.

Topic 303: Mental Health Science Education Materials for Social Work Faculty at Doctoral, Master's and Baccalaureate Programs

Finalized Work Plan- 5 copies- Within first 2 weeks of Phase II contract
Draft Final Report- 5 copies- At least 3 weeks prior to the end of the contract
Final Report- 5 copies- Due at contract expiration
Monthly Progress- 2 copies, submitted within 2 weeks of month ending and with the monthly invoice(1 to PO, 1 to CO)
Presentations at NIMH- 3 visits: first visit shall be within 1 month of contract award date to discuss the work plan; second visit shall be during contract performance and; third visit within the last month of contract to discuss the final report.

C. PAYMENT

The Government may make payments, including invoice and contract financing payments, by electronic funds transfer (EFT). As a condition to any payment, the contractor is required to provide information required to make payment by EFT. This information, if needed, may be requested under "just in time" procedures.

D. LIMITED RIGHTS INFORMATION AND DATA

Proprietary Information. Information contained in unsuccessful proposals will remain the property of the offeror. The Government, however, may retain copies of all proposals. Public release of information in any proposal will be subject to existing statutory and regulatory requirements.

The Department of Health and Human Services (HHS) recognizes that, in responding to this Solicitation, offerors may submit information that they do not want used or disclosed for any purpose other than for evaluation. Such data might include trade secrets, technical data, and business data (such as commercial information, financial information, and cost and pricing data). The use or disclosure of such information may be restricted if offerors identify it and the Freedom of Information Act (FOIA) does not require its release. For information to be protected, offerors must identify in the Notice of Proprietary Information (on the Proposal Cover Sheet) the page(s) on which such information appears. Any other Notice may be unacceptable to the Government and may constitute grounds for removing the proposal from further consideration without assuming any liability for inadvertent disclosure. Unless disclosure is required by the FOIA, as determined by FOI officials of the HHS, data contained in those portions of a proposal that have been identified as containing restricted information, in accordance with the Notice of Proprietary Information, shall not be used or disclosed except for evaluation purposes.

The HHS may not be able to withhold data that has been requested pursuant to the FOIA, and the HHS FOI officials must make that determination. The Government is not liable for disclosure if the HHS has determined that disclosure is required by the FOIA. If a contract is awarded to the offeror as a result of, or in connection with, the submission of a proposal, the Government shall

have the right to use or disclose the data to the extent provided by law. Proposals not resulting in a contract remain subject to the FOIA.

Rights to Data Developed Under SBIR Funding Agreement. Rights to data, including software developed under the terms of any funding agreement resulting from a contract proposal submitted in response to this Solicitation, shall remain with the awardee. However, the Government shall have the limited right to use such data for internal Government purposes and shall not release such data outside the Government without permission of the awardee for a period of four years from completion of each phase of the project under which the data was generated.

Copyrights. The awardee may normally copyright and publish (consistent with appropriate national security considerations, if any) material developed with NIMH support. The awarding component receives a royalty-free license for the Federal Government and requires that each publication contain an acknowledgement of agency support and disclaimer statement, as appropriate. An acknowledgement shall be to the effect that:

"This publication was made possible by contract number from (NIMH)" or "The project described was supported by contract number from (NIMH)."

Patents. Small business concerns normally retain the principal worldwide patent rights to any invention developed with Government support. Under existing regulations, 37 CFR 401, the Government receives a royalty-free license for Federal Government use, reserves

Original plus 2 copies the right to require the patent-holder to license others in certain circumstances, and requires that anyone exclusively licensed to sell the invention in the United States must normally manufacture it substantially in the United States. To the extent authorized by 35 U.S.C. 205, the Government will not make public any information disclosing a Government-supported invention for a four-year period to allow the awardee a reasonable time to file a patent application, nor will the Government release any information that is part of that application.

Inventions must be reported promptly—within two months of the inventor's initial report to the contractor organization—to the Division of Extramural Inventions and Technology Resources, NIH, at the address above. This should be done prior to any publication or presentation of the invention at an open meeting, since failure to report at the appropriate time is a violation of 35 USC 202, and may result in loss of the rights of the small business concern, inventor, and Federal Government in the invention. All foreign patent rights are immediately lost upon publication or other public disclosure unless a United States patent application is already on file. In addition, statutes preclude obtaining valid United States patent protection after one year from the date of a publication that discloses the invention.

The reporting of inventions can be accomplished by submitting paper documentation, including fax, or electronically through the NIH Edison Invention Reporting System. Use of the Edison system satisfies all mandated invention reporting requirements and access to the system is through a secure interactive Web site http://www.iedison.gov to ensure that all information

submitted is protected. In addition to fulfilling reporting requirements, Edison notifies the user of future time sensitive deadlines with enough lead-time to avoid the possibility of loss of patent rights due to administrative oversight. Edison can accommodate the invention reporting need of all organizations. For additional information about this invention reporting and tracking system, visit the Edison home page cited above or contact Edison via email at Edison@od.nih.gov.

Sharing Biomedical Research Resources. It is the policy of the NIH that unique research resources developed with NIH funding must be shared with the research community. Restricted availability of these resources can impede the advancement of research. Principles and Guidelines for Recipients of NIH Research Grants and Contracts, as published in the Federal Register Notice on December 23, 1999 http://ott.od.nih.gov/NewPages/RTguide_final.html, provide assistance to determine reasonable terms and conditions for acquiring and disseminating research tools, consistent with the objectives of furthering biomedical research and adhering to the Bayh-Dole Act.

Royalties. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

1. Name and address of licensor.
2. Date of license agreement.
3. Patent numbers.
4. Patent application serial numbers, or other basis on which the royalty is payable.
5. Brief description (including any part or model number of each contract item or component on which the royalty is payable.)
6. Percentage or dollar rate of royalty per unit.
7. Unit price of contract item.
8. Number of units.
9. Total dollar amount of royalties.
10. If specifically requested by the CO, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37.)

E. PERFORMANCE OF RESEARCH AND ANALYTICAL WORK

In Phase I projects, two-thirds or 67% of the research or analytical effort must be performed by the small business concern, i.e., subcontracts for portions of the scientific/technical effort and consultant fees should not exceed 33% of the total cost breakdown.

Contract Clauses. Upon entering into a contract, the contractor agrees, in accordance with the terms and conditions of the contract, to accept certain legal commitments embodied in the clauses of Phase I contracts. The general clauses and provisions located in the file "General Clauses" at URL: http://amb.nci.nih.gov/clauses/clauses.html apply to an SBIR Phase I Fixed-Price Research & Development Contract.

The following list illustrates the types of clauses to which a contractor is bound. **Clauses That Apply to Contracts *NOT* Exceeding $100,000:**

1. ***Standards of Work.*** Work performed under the contract must conform to high professional standards.

2. ***Inspection.*** Work performed under the contract is subject to Government inspection and evaluation at all times.

3. ***Termination for Convenience.*** The Government may terminate the contract at any time for convenience if it deems termination to be in its best interest, in which case the contractor will be compensated for work performed and for reasonable termination costs.

4. ***Disputes.*** Any dispute concerning the contract that cannot be resolved by agreement shall be decided by the CO with right of appeal.

5. ***Equal Opportunity.*** The contractor will not discriminate against any employee or applicant for employment because of race, color, religion, sex, or national origin.

6. ***Affirmative Action for Veterans.*** The contractor will not discriminate against any employee or applicant for employment because he or she is a disabled veteran or veteran of the Vietnam era.

7. ***Affirmative Action for Handicapped.*** The contractor will not discriminate against any employee or applicant for employment because he or she is physically or mentally handicapped.

8. ***Gratuities.*** The Government may terminate the contract if any gratuities have been offered to any representative of the Government to secure the contract.

9. ***American-made Equipment and Products.*** When purchasing equipment or products under an SBIR contract award, the contractor shall purchase only American-made items whenever possible.

Clauses That Apply to Contracts Exceeding $100,000 *In addition to the foregoing clauses, the following clauses apply to contracts expected to exceed $100,000*:

10. ***Examination of Records.*** The Comptroller General (or a duly authorized representative) shall have the right to examine any directly pertinent records of the contractor involving transactions related to this contract.

11. ***Default.*** The Government may terminate the contract for default if the contractor fails to perform the work described in the contract and such failure is not the result of excusable delays.

12. ***Contract Work Hours.*** The contractor may not require an employee to work more than eight hours a day or forty hours a week unless the employee is compensated accordingly (i.e., overtime pay).

13. ***Covenant Against Contingent Fees.*** No person or agency has been employed to solicit or secure the contract upon an understanding for compensation except bona fide employees

or commercial agencies maintained by the contractor for the purpose of securing business.

14. ***Patent Infringement.*** The contractor shall report each notice or claim of patent infringement based on the performance of the contract.

F. ADDITIONAL INFORMATION

1. If there is any inconsistency between the information contained herein and the terms of any resulting SBIR contract, the terms of the contract are controlling.
2. The Government is not responsible for any expenditures of the offeror in advance and in anticipation of an award. In a Phase II (typically a cost-reimbursement type contract), reimbursement of costs by the Government may be made only on the basis of costs incured by the contractor after award and during performance.
3. This Solictation is not an offer by the NIMH and does not obligate the NIMH to make any specifici number of awards. Awards under this program are contingent upon the scientific/technical merit of proposals and avialabiltiy of funds.
4. The SBIR program is not intended as amechanism to invite unsolicited proposals. Unsolicited proposals shall not be accepted under the SBIR program in either Phase I, Phase II, or under Fast Track Procedures.
5. If an award is made prusuant to a proposal submitted in response to this SBIR solicitation, the contractor will be required to certify that he/she has not previously been, nor is currently being, paid for essentially equivalent work by any agency of the Federal Government.

VIII. INSTRUCTIONS FOR PROPOSAL SUBMISSION [Back to Page 2]

Any proposal received after the exact time specified in the cover letter will not be considered unless it is received before award is made and:

1. It was sent by registered or certified mail not later than the fifth calendar day prior to the date specified for receipt of proposals;
2. It was sent by mail or hand-delivered and it is determined by the Government that the late receipt was due primarily to mishandling by the Government after receipt at the Government installation;
3. It was transmitted through an electronic commerce method authorized by the CO and was received at the initial point of entry to the government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals;
4. It is the only proposal received, or;
5. It is received in the office designated for receipt of proposals on the first workday on which normal Government processes are resumed following an emergency or anticipated event that interrupts normal Government processes so that proposals cannot be received by the exact time specified in the solicitation. Despite the specified receipt date above, a proposal received after that date may be considered if it offers significant costs or technical advantages to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

IX. RESEARCH TOPICS [Back to Page 2]

Topic 301: Development of Curriculum, Training Modules and Approaches to Increase Diversity of SBIR Technology Transfer Programs at the NIMH ***(Eligible for Fast Track Procedures)***

Currently the Division of Services and Interventions Research (DSIR) and the Division of Mental Disorders, Behavioral Research and AIDs (DMDBA) support a growing number of SBIR grants and contracts based on the rapidly expanding science of their research portfolios. However, the number of small businesses applying for (and receiving) these grants and contracts remains relatively homogeneous in terms of ownership and principal investigator. The number of applications submitted by ethnic minorities, women, individuals with disabilities, geographically diverse (e.g., rural; Hawaii, Alaska, Puerto Rico) and areas suffering from severe economic hardship (including ramifications post 9/11) remains relatively low.

The purpose of this contract is to develop and pilot test a set of curriculum, training modules and approaches to increase the diversity and quality of SBIR's being supported by DSIR (http://www.nimh.nih.gov/dsir/index.cfm) and DMDBA (http://www.nimh.nih.gov/dmdba/index.cfm) through both the contract and grant mechanism. *The focus must be on assisting diverse SBIRs develop proposals that are directly relevant to the research missions supported by one of these NIMH divisions.* During Phase I the contractor will develop curriculum, training materials, and ongoing mentoring and recruitment strategies that can be deployed at a national, regional, state or local level. Strategies may include on-site training, web-based resources, teleconferences, video, phone based approaches or a combination of approaches. The focus of the training may be directed toward any or all of the populations enumerated above. The focus of the technology transfer may be based on any of the individual or multiple scientific portfolio's supported by DSIR and/or DMDBA. It is expected that the contractor will work closely with DSIR and DMDBA SBIR program staff in the final identification of areas of scientific interest.

A contractor shall, at a minimum:

1. demonstrate an understanding of the array of barriers that contribute to the lack of submission by and awards to diverse SBIRs and plans to address each barrier;
2. demonstrate availability of scientific resources in the mental health research area of focus;
3. demonstrate availability of appropriate technology and business resources;
4. provide a description of the way in which potential under represented SBIR applicants will be identified;
5. provide a description and rationale of outcome criteria and evaluation plans (an economic analysis must be included); and
6. have a clear plan/strategy for providing constructive feedback /assistance to participating diverse SBIRs who are not successful with their first submission.

In addition, the contractor must provide a rough content outline of the curriculum and training materials and provide a rationale for each approach and strategy. The contractor shall include

focus groups, pilot studies and other means to establish usability. In addressing these areas the contractor must demonstrate an understanding of specific DSIR/DMDBA research portfolios and tailor their proposal accordingly. Since these materials and strategies are meant to help overcome obstacles for diverse SBIRs and supplement existing SBIR activities supported by the NIH and the SBA, the contractor shall address these issues in the business proposal.

Phase II will involve the completion of a fully developed, tested and evaluated set of materials, curriculum and strategies for providing technical assistance to the targeted diverse SBIRs. Since it is likely that several different model strategies will be developed and compared during the pilot test, the contractor shall develop a cost-benefit analysis as part of the final report.

The NIMH will consider longer periods of time than the standard 6 months for Phase I and 24 months for Phase II for highly meritorious and compelling submissions.

Topic 302: Development of Educational Models and Procedures to Improve the Quality of Mental Health Services and Interventions Research Mentoring ***(Eligible for Fast Track Procedures)***

There is general consensus within the scientific community that mentoring is a core component of the research training process. However, relatively little has been done to systematically improve the quality of research mentoring in general, and mental health services and interventions research mentoring in particular. Intensive short term mentoring programs supported by the NIMH (e.g., generally supported under the "R25 mechanism" such as the UCSD Summer Research Institute in Geriatrics) as well as more traditional approaches have successfully produced junior and mid-level researchers -- now serious attention needs to be given to the specific skills such successful mentors utilize and to capture these skills in a way that they can be taught to others.

The purpose of this contract is to develop a set of interactive educational materials and procedures to assist individuals engaged in the training and career development of mental health services and interventions researchers to develop and refine their mentoring competencies. For Phase I and Phase II of this SBIR, the focus of these models and procedures must be relevant to the research supported by the Division of Services and Interventions Research (DISR), NIMH (http://www.nimh.nih.gov/dsir/index.cfm). For example, prototypes might focus on general areas such as research on geriatric/adult/child interventions and/or services. Approaches may include face-to-face training, web-based skills development, manuals, CD-ROM or other techniques provided that there is empirical evidence supporting their use. A combination of approaches may also be proposed.

For Phase I and Phase II, mentors are broadly defined as individuals engaged in helping mentees transition to independent research careers in areas relevant to the research mission of the DSIR. Although the prototype should be focused on DSIR-related research in relationship to academic institutions, the proposal should address how the prototype might be expanded to larger audiences.

The following products shall be *developed in draft format* during Phase I of this contract:

1. a data-base/compendium of best practices (including, when appropriate, examples from executive development/business models);
2. content material in the core competency areas relevant to mentoring mental health intervention and services researchers;
3. prototype modules for corresponding competency areas and outcome measures for competencies that incorporate the perspective of multi-informants (e.g. peers, mentees);
4. criteria and procedures for certifying research mentors (at a minimum criteria should include: methods for assessing and establishing competence at core mentoring skills; proficiency at mentoring special populations and distance mentoring; evidence of time spent mentoring and mentees' research productivity; participation in continuing education to update mentoring skills); and
5. a strategy for evaluating the resultant training materials and procedures.

At a minimum the core competencies should include modules related to: grantsmanship skills and obtaining independent funding; assessing and enhancing research skills (e.g., guidance to individuals for enhancing methods, research content, statistics, data analysis etc. based on an evaluation of the mentees needs); research "good citizenship" skills (e.g., ethics, working with diverse communities, becoming a mentor etc.); and career development skills not commonly taught in research graduate programs (e.g., executive management skills such as negotiation, time management, budget development and supervisory/human resource skills, crafting c.v.). Attention should also be given to competencies in areas relating to dissemination of research (e.g., presenting results at professional conferences, preparing submissions for peer-review journals and other publication outlets, reviewing publications, servicing as editor etc).

In developing strategies, modules and other products the contractor should draw upon a wide array of methods and techniques from education, psychology, evaluation and business/management as well as existing research training/mentoring paradigms. Principles from these areas, as well as input from successful mentors and mentees, should guide the identification of best practices, ground the training of mentoring skills with state-of-the-art modes/methods of instructions, and contribute to the selection of measures for evaluating mentor/mentee outcomes. By the end of Phase I materials and procedures should be fully developed for at least two (2) core competency areas. The contractor may propose to develop these prototypes based on pilot testing, focus groups or other evidence based approaches during Phase I. The remaining competency areas should be developed sufficiently to judge adequacy for further development, testing and evaluation during Phase II.

The contractor shall propose a process to assure that the perspectives of senior and mid-level research mentors and individuals currently being mentored as well as representatives from appropriate scientific disciplines are included.

Phase II will involve the completion of a fully developed, tested and evaluated set of modules consisting of all necessary materials, curriculum and strategies for providing technical assistance to junior and senior researchers to enhance their mentoring skills. Since it is likely that several different model strategies will be developed and compared during the pilot test activities, the

contractor shall develop a cost-benefit analysis as part of the final report. The final report shall also include an evaluation of the modules suitable for publication in relevant journals.

The NIMH will consider longer periods of time than the standard 6 months for Phase I and 24 months for Phase II for highly meritorious and compelling submissions.

Topic 303: Mental Health Science Education Materials for Social Work Faculty at Doctoral, Master's and Baccalaureate Programs ***(Eligible for Fast Track Procedures)***

The past several decades of research have established significant knowledge on brain and behavior, diagnosis, and effective treatments and services for persons with mental illness. Unfortunately, the mental health care typically received often does not reflect this knowledge, which not only compromises the health and quality of life of persons in treatment or in need of treatment, but also the credibility of mental health services providers in general. This disparity highlights the need to better communicate to clinicians the research that can provide an empirical foundation to their clinical practice, enabling them to provide the best possible care to consumers throughout the course of illness. One avenue for such communication is to ensure that mental health professionals-in-training understand the science, technology, and products of state-of-the-art mental health research.

Social work practitioners provide a very large proportion of mental health services within the formal mental health care system and across the spectrum of health and human services. They also compose a significant proportion of the administrative personnel who manage public and private mental health services agencies. This suggests that improving the ability of social work clinicians' to read, interpret, and apply empirical research to clinical practice has great potential for improving quality of mental health care for a broad number of consumers. In addition, such exposure to research may provide the added benefit of increasing the number of social workers who seek careers or roles in mental health research.

Therefore, to address these issues, this contract will identify and develop innovative education and training materials that will substantially improve scientific literacy of and the application of empirical research to clinical practice by social work teaching faculty and field instructors at the doctoral, master's and baccalaureate levels, with a specific focus on mental health related research. The goal is to enable such faculty to enable students to also gain this knowledge and ability.

Phase I will involve the development of a model curriculum in mental health for social work students at the master's and doctoral level. The curriculum will emphasize the empirical basis of mental health research on brain and behavior, diagnosis, and effective treatments and services for persons with mental illness. The information should be scientifically valid and objective, appropriate to educational level, and should be readily teachable and integratable into existing post-secondary programming. Project design shall address performance objectives in relation to the chosen educational levels and topic areas.

The materials identified and/or developed shall include both background information and instructional guidance for social work teaching faculty, and shall facilitate the teaching of health

science concepts, statistical methods, and related disciplines. The materials should promote active faculty-guided and student-conducted intellectual inquiry. Project design shall address instructional objectives.

Curricula activities shall center around guided reading, guided classroom discussion, and cooperative learning activities in small groups with access to resource materials and with group synthesis and presentation of information. Problem focused activities are encouraged. Resulting materials should utilize educational technologies as appropriate. Project design shall address the selection of instructional technologies/media, and should include evidence of plans to ensure consultation with faculty, NIMH project officers, and other mental health researchers. Project design shall also address the use of focus groups and interactive processes for vetting materials to assure that they reflect current scientific knowledge and/or field testing, as appropriate. Evaluation components to assess student learning, appropriateness of materials and strategies to educational level, and faculty satisfactions or instructional difficulties shall be included.

Phase II will involve the completion of a fully developed, tested and evaluated set of materials, curriculum and strategies. In addition to the materials, curriculum and strategies developed, the Final Report shall include an outcome evaluation.

The NIMH will consider longer periods of time than the standard 6 months for Phase I and 24 months for Phase II for highly meritorious and compelling submissions.

Topic 304: Use of Computer-based Technology to Deliver Effective HIV Prevention Interventions

Since 1983, the NIMH Center for Mental Health Research on AIDS (CMHRA) has supported research activities related to the primary and secondary prevention of AIDS and the neurobehavioral consequences of HIV infection. The Center, a component of the Division of Mental Disorders, Behavioral Research and AIDS of the NIMH, currently supports studies concerned with prevention strategies to curb the spread of HIV, identify the effects of HIV on the central nervous system, define HIV-related neuropsychological and neuropsychiatric disorders, and improve mental health services relevant to HIV infection.

In recent years, leading public health organizations have begun to advocate several important changes in the fight against HIV, such as improving health service providers' capacity to screen, assess and intervene with individuals whose behaviors confer risk for HIV infection or transmission. Recent epidemiological trends underscore the need to enhance accessibility of prevention programming for various segments of the population, including socially and economically disadvantaged individuals, men who have sex with men (MSM), and persons infected with HIV. In addition to enhancing quality of life, improving treatment outcomes, increasing adherence to treatment, and reducing the burden of disease, interventions that can be delivered using computer-based technology in resource-strained settings may help to curb the spread of HIV to uninfected persons. The considerable time, skill, and economic demands associated with HIV prevention suggests the need to maximize existing resources to increase education, enhance motivation for change, and impart behavioral skills necessary to enact risk reduction successfully and in the face of challenging circumstances. Innovative, empirically-

supported, cost-effective, computer-augmented interventions may mitigate barriers common to these and other settings.

The purpose of this contract is to support the development and testing of computer-based technology (e.g., CD-ROM, Internet, hand-held devices) in the adaptation, piloting, and implementation of theoretically-based, empirically-supported primary and secondary HIV prevention interventions that target risk behaviors, particularly for individuals at highest risk of transmission or infection and in settings with little time and few resources for prevention programming. For the purposes of this contract, primary prevention refers to efforts to reduce incident HIV infections through targeting infected or uninfected persons. Secondary prevention refers to reducing the burden of disease among persons living with HIV by addressing access to treatment, treatment adherence, and quality of life.

Suitable projects that adapt effective theoretically-based, empirically-supported HIV prevention interventions to digital environments (e.g., web sites, CD-based programs, software) may include but are not limited to:

- Training or assisting health care providers to conduct HIV risk screening and behavioral counseling;
- Improving adherence to medical treatment among persons living with HIV;
- Advancing computerized assessment technology that can be transferable to a range of community and clinical settings that minimize participant burden, fit seamlessly into busy service centers, and yield reliable and valid behavioral data necessary to assess behavior change pre- and post-intervention;
- Delivering behavioral intervention aimed at hard to reach segments of the population, including, marginally/housed, older men, discordant couples, etc;
- Evaluating the efficacy and effectiveness of HIV prevention/health kiosks in clinical care settings that permit self-assessment of risk and facilitate discussion with health care providers about current risks and methods for minimizing transmission to others.

ATTACHMENT N0. 1

PROPOSAL INTENT RESPONSE SHEET [Back to Previous Page]

Under NIMH SBIR Solicitation No. NIMH-03-SBIR-PhaseI

PLEASE REVIEW THE ATTACHED REQUEST FOR PROPOSAL. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY APRIL 30, 2003 TO THE ADDRESS SHOWN BELOW. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

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SBIR TOPIC NO. AND TITLE:

_____

[ ] DO INTEND TO SUBMIT A PROPOSAL

[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

COMPANY/INSTITUTION NAME:

_____

AUTHORIZED SIGNATURE:

_____

TYPED NAME AND TITLE:

_____

DATE: _____

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RETURN TO:
National Institute of Mental Health
Contracts Management Branch, ORM
Attn: Robin Hope-Williams, Contract Specialist
6001 Executive Boulevard
Room 8154, MSC 9661
Bethesda, Maryland 20892-9603
Tel: 301-443-2696
Fax: 301-443-0501